

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I (claims 1-7) in the reply filed on 2/22/08 is acknowledged. Following election of species: LYRAD, with LYRAD-COSR<sup>6</sup> being the thioester form with t-butyl as R<sup>6</sup>, and phenacyl ester as the protecting group of D and having the formula -CH(R<sup>13</sup>)-CO-(C<sub>6</sub>H<sub>4</sub>)-R<sup>14</sup>, where R<sup>13</sup> and R<sup>14</sup> are methyl as the "first oligopeptide". species of SEQ ID NO: 6, CSYRFL as the "second oligopeptide" is acknowledged.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claims 1-11 are pending.

Claims 8-11 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-7 are examined on the merit.

A prior art search indicated that the elected species is free of prior art. The search was extended to additional species of claim 2 and were found to be free of prior art.

***Allowable Subject Matter***

Claim 2-7 have objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant invention applicants claim a method of chemically ligating two oligopeptides wherein the first oligopeptide thioester having an acidic C-terminal oligopeptide thioester having a thioester moiety, a side chain, and a side chain protecting group such that said side chain protecting group substantially prevents rearrangements between atoms of said side chain and atoms of said thioester moiety, is contacted with a second oligopeptide having an N-terminal amino acid under chemical ligation conditions such that said thioester moiety of said first oligopeptide thioester ligates to said N-terminus of said second oligopeptide to form a polypeptide product.

The claims as recited encompass any and all known and unknown C-terminal protecting groups. The claim as recited encompass C-terminal protecting groups described only by its function without divulging the chemical structure of the protecting groups associated with the intended function. Lack of adequate disclosure of partial or complete structural features and physical and/or chemical properties associated with functional characteristics of the compounds of moieties recited in the invention would lead one of skill in the art to the conclusion that the applicant was not in possession of the claimed invention.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient” MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

In addition to this, applicants disclose the following criteria with regards to "Selection of side chain protection for Glutamyl Thioesters". "To avoid this undesired side reaction, preferably a protecting group is selected for the side-chain carboxy that has the following characteristic: (i) stable to I-IF cleavage; (ii) stable during the ligation reaction; and (iii) easily removed after the ligation reaction, preferably under conditions that will not jeopardize the integrity of a fully deprotected protein. Most of the available protecting groups will not withstand the first requirement. The following protecting groups were selected for this experiment: 9-fluorenylmethyl ester (OFm) and (phenylsulfonyl)ethyl ester (OPse) [0070]".

Hence the disclosure as originally filed does not adequately support the claims commensurate with the scope of the claims as recited in the instant application. Therefore, the claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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